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As time goes by

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TITLE PAGE

As time goes by

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Fictional scenario

An orthodontist reads the previous piece in the Journal about investigating the prevalence of gingival recessions after orthodontic treatment (Papageorgiou, 2020). His curiosity is awoken and wants to check what would be the corresponding prevalence of post-orthodontic gingival recessions among his own patients. More importantly, following a recent talk in a scientific congress, he decided 5 years ago to change the treatment protocol for his non-extraction cases. He now prophylactically uses a free gingival graft on the labial side of incisors before starting treating cases with a very thin gingival biotype when arch expansion / protrusion has been planned. He therefore likes to see if this new treatment protocol is effective in preventing gingival recessions.

He collects all non-extraction cases treated in his practice 4 years prior and 4 years after he implemented this new treatment protocol. He uses the detailed intraoral photographic documentation after treatment to assess the presence of at least one gingival recession and set this as his outcome. He finds 300 eligible patients from his archives, who are equally divided in the two treatment protocols. Among the 300 patients analysed, 99 (33%) of them have at least one recession after treatment and both groups seem to have similar prevalence of recession: 56 out of 150 patients (37.3%) with the old protocol and 43 out of 150 patients (28.7%) with the new protocol (Table 1). He did a chi-square test to compare the proportion of patients with recessions in the two groups, which gave a P value of 0.11. Furthermore, he thought that the duration of orthodontic treatment might act as a confounder and might contribute to the development of recessions. He likewise extracted these data from the patient archives and compared them between groups. The overall median treatment duration for all patients was 24.1 months and this was similar in the two groups: 24.2 months in the old protocol and 24.1 months in the new protocol. As treatment duration was not normally distributed, he used a Mann-Whitney test to compare durations between groups, which gave him a P value of 0.70

Which of the following statements are correct regarding the interpretation of the study's results, if any:

- (A) No statistically significant difference exists in the development of gingival recessions with the two treatment protocols.
- (B) Treatment duration has been adequately handled as a confounder and cannot influence the study's conclusions.
- (C) Treatment duration has no significant effect on the development of gingival recessions.
- (D) The risk for developing recessions according to this study sample is 33%, with no differences according to protocol and treatment duration.

Discussion

In order to correctly appraise the results of this study, one needs to first appraise how they were analysed. And the analytical strategy is heavily dependent from the type and nature of the observation we are talking about. In this instance the outcome data are binary – i.e. recession: yes or no. Therefore, a chi-squared test might be an appropriate first step to check for differences between the two protocols.

Additionally, data are given about the duration of orthodontic treatment. This might be interesting, since intuitively duration might be associated with baseline malocclusion severity or with the oral health burden, thereby indirectly affecting recession risk. What is actually known about treatment duration for the included patients? We know that the average treatment duration is a sensible one (based on the orthodontic literature), as well as that the average treatment duration is similar in the two protocol groups and about 2 years. This does not mean however that all patients in the two groups had a 2-year (24-month) treatment. Looking carefully at the data, treatment duration varies considerably for the 300 studied patients: (i) the duration for 100 patients (33.3%) was up to 12.0 months, (ii) for 45 patients (15.0%) was 12.1-24.0 months, (iii) for 99 (33.0%) patients was 24.1-36.0 months, and (iv) for 56 (18.7%) patients was >36.0 months. This is not to

say that the two groups are different according to their distribution of these duration categories (they are not—the chi-squared P value is 0.28). But this indicates that the studied group is very heterogenous in terms of treatment duration. This is a common problem seen in retrospective studies that make use of routinely available material in sharp contrast to prospective randomized trials, where all patients might receive exactly (or almost exactly) the same exposure from an intervention – i.e. might be all consistently followed for 1 or 2 years.

Given the big range of treatment duration (from 8.4 to 40.0 months) it is interesting to see how recessions develop within that timeframe. As can be seen in (Figure 1) more recessions are developed among the studied patients the longer the treatment takes. To put thing into perspective, the recession risk for durations <24.0 months is 34/140 (24.3%), while the recession risk for durations >24.0 months is 65/159 (40.9%). This can be modelled statistically giving a Relative Risk (RR) of 1.18 (95% Confidence Interval [CI]=1.07 to 1.29; $P<0.001$) per 6-month-period, which means that for each additional 6 months of treatment duration the recession risk increases by 18%. Therefore, pooling simply all patients and analyzing them naively with a chi-squared test as the orthodontist did, might not be the best treatment approach.

Instead, a survival analysis taking into account the different times that a patient is 'exposed' to the risk (i.e. the time in fixed-appliance treatment) might be more appropriate. Indeed, such an analysis gives a Hazard Ratio (HR) of 0.66 (95% CI=0.44 to 0.98) with a P value of 0.04. We see therefore that the new protocol is associated with a significantly reduced hazard for recession by 34%. If we plot this in similarly in a Kaplan-Meier survival curve (Figure 2), it is obvious that the two lines end up differently, particularly for longer treatment durations. This gives different results than the original analysis plan that was followed and therefore it is always important that such time-varying situations are appropriately tackled.

To summarize, the conclusions of the original study might be misleading and (A) is wrong. Treatment duration was not properly handled in the original analysis and (B) is wrong. Treatment duration in this fictional example was significantly associated with baseline risk for recessions and

(C) is wrong. And finally, the recession risk varied considerably according to both duration and treatment protocol. For durations <24.0 months recession rate was 25.7% and 22.9% for the old and new protocol, respectively. For durations >24.0 months recession rate was 48.1% and 33.8% for the old and new protocol, respectively, and (D) is wrong.

Table 1. Results of the survey performed by the orthodontist.

	Total	Old protocol	New protocol	Test	P
Patients – n	300	150	150		
No recession – n (%)	201 (67.0%)	94 (62.7%)	107 (71.3%)	Chi-squared	0.11
Recession – n (%)	99 (33.0%)	56 (37.3%)	43 (28.7%)		
Duration in months – Median (IQR)	24.1 (10.8, 34.7)	24.2 (10.8, 34.2)	24.1 (10.9, 35.6)	Mann-Whitney	0.70

IQR, interquartile range.

Figure 1. Kaplan-Meier survival curve for the whole sample.

Figure 2. Kaplan-Meier survival curve separately for the two treatment protocols.

References

Papageorgiou SN (2020) Proper case selection and assessment. *Journal of Orthodontics* 47: 185–186.